

REMARKS

Reconsideration of this application, as amended, is respectfully requested.

In the Official Action, the Examiner indicates that formal drawings cannot be found for the present application and requests that formal drawings are submitted with a response to the Official Action. In response, a set of drawings is enclosed herewith. Also enclosed is a copy of the transmittal sheet filed with the present application indicating that 4 sheets of formal drawings were submitted at the time of filing.

In the Official Action, the Examiner objects to the Abstract because of the inclusion of legal phraseology, because it is not in the form of a single paragraph, and because the Examiner feels that the last line thereof should be deleted. In response, the Abstract has been amended to delete the legal phraseology, to put it in a single paragraph format, and to delete the last line. Accordingly, it is respectfully requested that the objections to the Abstract be withdrawn.

In the Official Action, the Examiner rejects claims 1-8 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner requests that "preferably" on line 1 of claim 1 be deleted since it renders the scope of claim 1 indefinite. Furthermore, the Examiner argues that there is improper antecedent basis for the phrase "the commissural points" on line 3 of claim 1. In response, claim 1 has been amended to delete --,preferably, a cardiac valve prosthesis,-- and to change "the commissural points" to --commissural points--. Furthermore, the claims have been further amended to improve their form and readability and to conform them to standard U.S. practice and style. In view of the above, it is respectfully requested that the rejection of claims 1-8 under 35 U.S.C. § 112, second paragraph, be withdrawn.

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In the Official Action, the Examiner rejects claims 1-8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,840,081. In response, in order to advance prosecution, Applicant files herewith a terminal disclaimer disclaiming any portion of the term of a U.S. patent, which eventuates from the present application, which extends beyond the term of U.S. Patent No. 5,840,081. Accordingly, the Examiner is respectfully requested to withdraw the rejection of claims 1-8 under the judicially created doctrine of obviousness-type double patenting.

In the Official Action, the Examiner also rejects claims 1-8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,411,552. In response, in order to advance prosecution, Applicant files herewith a terminal disclaimer disclaiming any portion of the term of a U.S. patent, which eventuates from the present application, which extends beyond the term of U.S. Patent No. 5,411,552. Accordingly, the Examiner is respectfully requested to withdraw the rejection of claims 1-8 under the judicially created doctrine of obviousness-type double patenting.

In the Official Action, the Examiner rejects claims 1-4 and 8 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,657,744 to Ersek (hereinafter "Ersek"). Furthermore, the Examiner rejects claims 5-7 under 35 U.S.C. § 103(a) as being unpatentable over Ersek. In response, Applicants respectfully traverse the Examiner's rejections under 35 U.S.C. §§ 102(b) and 103(a) for at least the reasons set forth below.

Ersek teaches a method for fixing a prosthetic implant in a body. In a preferred implementation discussed in Ersek and illustrated in Figures 3, 4, and 8, an aortic heart valve is implanted. The aortic heart valve is carried on a fixation sleeve (16). The fixation sleeve and heart valve are carried on an expansion tool. The expansion tool accesses the interior of the aorta by a longitudinal slit (an aortotomy) in the aorta, the fixation sleeve and replacement valve are put in place, the fixation sleeve is expanded,

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the expansion tool is removed from the slit, and the slit is clamped and eventually sutured. Thus, the devices and methods of Ersek are used in an open surgical procedure where the thoracic cavity is opened.

The present invention is directed to the implantation of valve prostheses by means of catheterization techniques. Such is recited in claim 1. The fixation sleeves disclosed in Ersek could not be compressed to the degree necessary to fit within a catheter. The mesh design of the fixation sleeves of Ersek offer very little compression. In fact, Ersek does not teach or suggest the compression of the fixation sleeves to a degree where they can fit within a catheter, only such that they can be moved after the initial placement. Therefore, claim 1 patentably distinguishes over Ersek and is allowable.

With regard to the rejection of claims 104 and 8 under 35 U.S.C. § 102(b), a valve prosthesis for use in a catheterization technique and as recited in independent claim 1 is nowhere disclosed in Ersek. Since it has been decided that "anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim,"<sup>1</sup> independent claim 1 is not anticipated by Ersek. Accordingly, independent claim 1 patentably distinguishes over Ersek and is allowable. Claims 2-4 and 8 being dependent upon claim 1, are thus allowable therewith. Consequently, the Examiner is respectfully requested to withdraw the rejection of claims 1-4 and 8 under 35 U.S.C. § 102(b).

With regard to claims 5-7 under 35 U.S.C. § 103(a), since independent claim 1 patentably distinguishes over the prior art and is allowable, claims 5-7 are allowable therewith because they depend from an allowable base claim.

In other words, Independent claim 1 is not rendered obvious by the cited

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<sup>1</sup> Lindeman Maschinenfabrik GMBH v. American Hoist and Derrick Company, 730 F.2d 1452, 1458; 221 U.S.P.Q. 481, 485 (Fed. Cir., 1984).



references because the Ersek patent, whether taken alone or in combination with the knowledge of those skilled in the art at the time of the invention, does not teach or suggest a valve prosthesis for use in a catheterization technique. Accordingly, claim 1 patentably distinguishes over the prior art and is allowable. Claims 5-7, being dependent upon claim 1, are thus allowable therewith. Consequently, the Examiner is respectfully requested to withdraw the rejection of claims 5-7 under 35 U.S.C. § 103(a).

Furthermore, Applicants respectfully submit that claims 3 and 5 patentably distinguish over Ersek independently of their base claim (1).

With regard to claim 3, the fixation sleeve illustrated in Figures 3 and 4 of Ersek does not have several spaced apices projecting from one side of the cylindrical structure of the valve prosthesis, as is recited in claim 3. Ersek teaches that the commissures of the valve are secured to the upper and lower ring portions (26, 27) of the fixation device. The upper and lower surfaces are illustrated as flat surfaces, not having any apices. Therefore claim 3 patentably distinguishes over Ersek and is allowable.

With regard to claim 5, the Examiner argues that the loop or serpentine pattern recited in claim 5 is well known in the stent art and would have been an obvious variant in view of its obvious advantages over the mesh design of Ersek. Applicants respectfully disagree.

Firstly, Applicants request that the Examiner make a showing of the knowledge of those skilled in the art at the time of the filing of the present application in support of his argument that a looped design is well known in the stent art. Specifically, Applicants request the Examiner to cite a reference showing such a design.

Secondly, even if the looped design were known in the art, those skilled in the art would not be motivated to modify Ersek with such a looped design because Ersek is not directed to catheterization, but to open surgical procedures. An advantage of the

looped design is the greater compression ratio that can be achieved, which is only an issue with catherization and not necessary with open surgical procedures such as that disclosed in Ersek.

Furthermore, the Examiner argues that providing loops of greater height would have been obvious from the purpose of the openings 25 or struts 28 illustrated in Ersek. Ersek states that the openings 25 are to permit exposure of wide areas around the coronary artery ostia. Although, the purpose of the struts 28 is not expressly stated in Ersek, it is assumed that they provide the same purpose as the openings 25. The loops of greater height recited in claim 5 form the apices to which the commissural points of the valve are attached. No such loops are taught or suggested in Ersek.

In view of the above, claim 5 also patentably distinguishes over Ersek and is allowable.

Attached hereto is a marked-up version of the changes made to the application by the current amendment. The attached page is captioned **"Version with Markings to Show Changes Made."**



In view of the above, it is respectfully submitted that this application is in condition for allowance. Accordingly, it is respectfully requested that this application be allowed and a Notice of Allowance issued. If the Examiner believes that a telephone conference with Applicant's attorneys would be advantageous to the disposition of this case, the Examiner is requested to telephone the undersigned.

Respectfully submitted,



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Enclosures    (Two Terminal Disclaimers;  
Four Sheets of Formal Drawings;  
Copy of Filing Transmittal sheet; and  
Version with Markings to Show Changes Made)